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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,205	12/12/2005	Tetsuya Suzuki	2005_1548A	2813

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EXAMINER	
SUTTON, DARRYL C	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,205	SUZUKI, TETSUYA	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2005, 10/01/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6, 7, 8 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term "base granule" in claim 6 and 7 renders the claims indefinite. The term "base" is appended to an otherwise definite phrase "granule", rendering the modifying function of the term "base" unclear, i.e. it is not clear how a "granule" is to be differentiated" from a "base granule"

The use of the word "type", i.e. cellulose type, in claims 8, 13, 15, 17 and 19 render the claims indefinite. For example, there is no way to ascertain how closely structurally a compound must be to cellulose to be considered cellulose type.

The use of the word "kind" in claims 2, 8, 13, 15, 17 and 19 render the claims indefinite. It is unclear what the selection/exclusion criteria for "kind" are. The examiner suggests deleting the term since it serves no apparent function and is not necessary to an understanding of the claimed term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al. (U.S. Patent Pub. 2002/0091152).

Abe et al. teach a medicament comprised of alkylenedioxybenzene derivatives of formula I and pharmaceutically acceptable salts thereof; hydrochloride salts are physiologically acceptable salts to be used in the present invention (Abstract, paragraphs [0009-0010] and [0017]). It is preferable to prepare a pharmaceutical composition comprising an active ingredient and one or more pharmaceutical additives (paragraph [0024]). Examples of pharmaceutical compositions include, formulations for oral administration such as tablets, capsules, subtilized granules and the like (paragraph [0024]). Tablets and capsules for oral administration are prepared by using ordinary pharmaceutical additives such as fillers such as cellulose, mannitol and lactose; diluents; disintegrating agents such as starch, polyvinylpyrrolidone. Tablets may be coated according to a well known method in the art, for example, by using an enteric coating agent, i.e. for controlled, sustained release (paragraph [0025]). Formulations for oral administration can be manufactured according to a method well

known in the art. In addition, it is also possible to disperse the active ingredient in a formulation containing a large amount of filler by repetitive mixing (paragraph [0027]).

The prior art anticipates the instant invention insofar as it discloses oral composition compositions comprised of substantially the same active ingredients; matrix, i.e. fillers; and dosage forms.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, 11 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al. as applied to claims 1-6 and 8-10, 12-20 above and in further view of Remington (1995).

Abe et al. is discussed above.

Abe et al. does not teach a matrix comprised of wax, nor does Abe et al. teach the active agent and wax matrix are coated with a coating agent containing a synthetic polymer.

Remington teaches that there are four categories of nonimmediate-release delivery systems including sustained, controlled release (page 1661). Some advantages of sustained release include, eliminating or minimizing patient compliance, a decrease or elimination of both local and systemic side effects, and improved efficiency of

treatment, i.e. optimized therapy (page 1662). An oral dosage form for sustained release is a matrix device, where a drug is dispersed as a solid in an inert matrix. The three major types of materials used in preparation of oral matrix devices are insoluble plastics, hydrophilic polymers and fatty compounds. Fatty compounds include various waxes such as carnuba wax; the drug is dispersed in the wax matrix and then granulated (page 1666-1667). Film coatings can be applied to pharmaceutical products in order to modify drug release. A controlled release, i.e. delayed release, film coating, such as an enteric coating, will allow the release of a drug to be extended over time by preventing drug release in the upper GI tract. Pharmaceutical formulators now prefer to used synthetic polymers to prepare more effective enteric coatings; the most extensively used synthetic polymer is cellulose acetate phthalate (pages 1653-1654, Modified-Release Film Coatings).

Remington does not teach that the active agent is an alkylenedioxybenzene derivative of formula I.

At the time of the invention, it would have been obvious to modify the composition of Abe et al. to include a matrix device and an enteric coating motivated by the desire to modify release of the active ingredient and thereby decrease or eliminate local and systemic effects and improve the efficiency of the treatment as taught by Remington.

It is prima facie obvious to select a compound based on its suitability for its intended purpose. See MPEP 2144.07. Therefore, it would have been obvious to use

cellulose acetate phthalate, i.e. cellulose-type synthetic polymer, as the enteric coating; and to use carnuba wax, i.e. synthetic wax, as the matrix material.

Claims 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al. and Remington as applied to claims 4, 5, 11 and 15-20 above and in further view of Itoh et al. (U.S. 5,194,464)

Abe et al. is discussed above.

Abe et al. does not teach a granule comprised of wax and an excipient coated with an enteric film.

Remington is discussed above.

Remington does not teach granules comprised of a wax matrix and excipient coated with an enteric coating.

Itoh et al. teach an enteric film comprised of a mixture of hydroxypropylcellulose phthalate, polyethylene glycol and shellac (Abstract, column 1, lines 51-53). Enteric coated granules do not produce individual variation in gastric emptying rate and absorption, and are free from influence by meals (column 1, lines 16-22). The pharmaceutical preparation to be covered with the said enteric film includes fine granules and granules obtained by extruding granulation (column 2, lines 31-35). Granules were produced by kneading the active ingredient; fillers, i.e. matrix; and excipients; and then producing granules by extruding granulation; then spraying the resulting granules with an enteric coating (column 10, lines 19-59).

At the time of the invention, it would have been obvious to modify the form of the composition suggested by combining Abe et al. and Remington to the enteric coated granules of Itoh et al., motivated by the desire to produce a pharmaceutical composition that has constant absorption rate and is not influenced by meals as taught by Itoh et al.; and, therefore also obvious use the method of preparation of the enteric coated granules of Itoh et al.

When the general conditions of a claim are disclosed in the prior art, it is not inventive to determine optimum or workable ranges through routine experimentation. Therefore, it would have been obvious to determine the optimum or workable ranges of wax in the matrix.

The release profile of the instant invention is dependent on the composition being prepared as claimed. The profile is determined as a result of the routine experimentation to determine the optimum or workable ranges of ingredients in the composition. The method of measuring the release rate is not novel and does not add materially to the invention.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612